

## Title (en)

FREEZE-DRIED PREPARATION CONTAINING HIGH-PURITY PTH AND METHOD FOR PRODUCING SAME

## Title (de)

GEFRIERGETROCKNETES PRÄPARAT MIT HOCHREINEM PTH UND VERFAHREN ZUR HERSTELLUNG DAVON

## Title (fr)

PRÉPARATION LYOPHILISÉE CONTENANT DE L'HORMONE PARATHYROÏDIENNE (PTH) DE HAUTE PURETÉ ET SON PROCÉDÉ DE PRODUCTION

## Publication

**EP 3020409 A1 20160518 (EN)**

## Application

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## Abstract (en)

[Problem] Provided is a freeze-dried preparation containing high-purity PTH peptide and a method for the production thereof. Also provided is a test method for PTH analogs to confirm the purity of a freeze-dried preparation containing PTH peptide, and the like. [Solution] In the present invention, the presence of PTH analogs produced during the manufacturing process of a freeze-dried preparation containing PTH peptide was confirmed. The production of these PTH analogs was also discovered to be markedly prevented or reduced by controlling exposure of the solution containing PTH peptide and the like to air environments within a pharmaceutical production facility.

## IPC 8 full level

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